SECTION 3

PHYSICIAN ADJUDICATION

INTRODUCTION

An outcome is adjudicated by assigning the appropriate outcome diagnosis based on Women's Health Initiative (WHI)-defined criteria for each condition and recording clinical and diagnostic information supporting the diagnosis on the outcomes form. Because of the complexity and number of outcomes for this study, it is imperative that physicians at each Clinical Center (CC) assume responsibility for the accurate adjudication of events. This final assignment of an outcome diagnosis will follow a multi-step, multi-component process of ascertainment as described in *Section 2 - Ascertainment*.

The Physician Adjudicator(s) at each CC has the responsibility for making all final assignments of diagnoses in the adjudication process and signing each outcome form indicating that he or she has done or overseen the diagnostic decision-making and agrees with the final diagnosis. Physicians doing adjudication must be familiar with general internal medicine principles, and in particular, with the diagnostic work-up of cardiovascular disease (CVD), cancers, and fractures.

The Physician Adjudicator is required to be blinded to randomized treatment assignment in Clinical Trial (CT) cases and to exposure status in Osteoporosis Study (OS) cases. Physician Adjudicators should also **not** be exposed to "effective" unblinding information (that might allow "educated guesses" to treatment arm), such as information that a Clinic Practitioner or Group Nutritionist might obtain during participant contacts (see *Vol. 2, Section 4.6.5 - Blinding Considerations and Recommendations*).

3.1 Physician Adjudicator Training

Before attempting outcomes adjudication, the Physician Adjudicator must complete a training process, which includes:

Reading:

- *Vol. 1 - Study Protocol and Policies, Section 1 - Protocol, Section 4.3 - Outcomes of Interest*
- All sections of *Volume 8 - Outcomes*.
- For physicians not currently familiar with reading electrocardiograms (ECGs), the following reading may be helpful:
    - Crow, R.S., Prineas, R.J., Jacobs, D.R., et al. (1989). A new epidemiologic classification system for interim myocardial infarction serial electrocardiographic changes. *American Journal of Cardiology*, 64:454-461.
    - Dubin, D. (1996). Rapid Interpretation of EKG's, 5th Ed. Tampa, Florida, Cover Publishing Co.
    - Goldschlager, N., and Goldman, M.J., (1989) *Principles of Clinical Electrocardiography*, 3rd ed. Norwalk, CT: Appleton and Lange.

Central Training:

- Participation either in adjudication training discussions at WHI meetings or on a Physician Adjudicator training conference call (Physician Ajudicators may participate in both, if desired).
- Additional training through the feedback provided from central adjudication of the major outcomes of interest and at selected regional meetings or at the annual general meeting.
- Regular communications, including updates with Physician Adjudicators via the "WHI Outcomes Consultation" (a CCC-produced newsletter).

3.2 Overview of the WHI Outcomes

WHI outcomes ascertainment and adjudication is achieved through a multi-step, multi-component process (see *Figure 1.1 - Local Ascertainment and Adjudication Process*). Within 3 months of first notification of a potential outcome, the CC adjudication process should be complete. Given the delays often inherent in obtaining records, it may at times not be possible to meet this 3-month deadline. However, all efforts should be made to obtain and process all documents in as expedient a manner as possible.

3.2.1 Ascertainment

Outcomes ascertainment activities are usually carried out by the Outcomes Specialist and/or outcomes staff. (See *Section 2 - Ascertainment*). Ascertainment includes:

- **Identification** - Possible WHI outcomes will be reported at regular semi-annual (CT) and annual (CT & OS) contacts, through completion of *Form 33 - Medical History Update* by the participant or, for deceased or debilitated participants, by a proxy. Additional potential outcomes may come to the attention of the CC through interim contacts with the participant or proxy or through other sources (such as the National Death Index, newspaper obituaries, returned mail or review of hospital documents collected for other outcomes).

  Identification of a potential outcome while reviewing hospital records and/or a report of death should be processed immediately. All other interim reports are collected at routine contacts and no investigation is required until that time.

  A participant whose *Form 33* indicates a potential outcome has occurred and additional provider information is required will be asked to complete a *Form 33D - Medical History Update (Detail).* Database analysis of this *Form 33D* or *Form 120 - Initial Notification of Death* will result in specific outcomes cases being created in the WHILMA database.

- **Investigation** - Providers identified by the participant are sent requests for medical record documents. These documents are tracked and re-requested as necessary to complete the required document set. (Note: Certain outpatient-diagnosed subsidiary WHI outcomes do not require documentation: diabetes mellitus, benign breast disease, colorectal polyp, cardiac cathetherization, arthritis, glaucoma.)
- **Documentation** - Documents are reviewed and assembled by the Outcomes Specialist to form an adjudication case packet, which is then "assigned" to a local Physician Adjudicator.

3.2.2 Local Adjudication

Local adjudication is the responsibility of each CC Physician Adjudicator, who receives the adjudication case packet prepared by the Outcomes Specialist, reviews it, and makes a decision to:

- Close the case as a WHI outcome;
- Close the case as "no WHI outcomes" for this adjudication.
- Request more documentation; or
- Request central adjudication (i.e., review of the case packet) for the case after making a "best" diagnosis and documenting why the case is forwarded for review.

3.2.3 Central Adjudication

In addition to local adjudication, certain cases may also require central adjudication. Central adjudication refers to a WHI diagnosis assignment by the appropriate central adjudicator, central adjudication committee, or CCC resource. Central adjudication occurs for purposes of quality assurance and additional coding.

Clinical Centers will be notified monthly about which locally adjudicated cases require central adjudication via a WHILMA database report or other CCC communication. The CC Outcomes Specialist will prepare the locally adjudicated case packets for central adjudication. (See *Section 2.5.2 - Routine Case Packets for Central Adjudication.*)

For those outcomes requiring central adjudication, a copy of the completed outcomes forms and the entire case packet will be sent to the CCC.

The submitted final documentation packet will be checked for completeness and legibility by the CCC outcomes staff. When the CCC finds a final case packet incomplete, it will contact the CC and report the deficiency. The case packet will be held in the CCC until the additional information is obtained.

3.2.3.1 Plan for Future Reduction in Number of Centrally Adjudicated Outcomes

The agreement between a particular CC Physician Adjudicator's decision and that obtained by central adjudication will be monitored centrally to determine subsequent percentages of locally-adjudicated cases that need to be sent for central adjudication. When a new CC Physician Adjudicator is added, 100% adjudication of certain outcomes will be instituted for that CC Physician Adjudicator until the agreement between local and central adjudication warrants reducing the percentage of cases that need to be sent centrally.

3.2.3.2 Central Adjudication Working Groups

Central adjudication of cardiovascular outcomes will be done by the Cardiovascular Central Adjudication Working Group.

This group will adjudicate primarily via mail, after central CVD adjudication meetings have been held to establish procedures. Conference calls and meetings are also anticipated to follow-up on discrepancies and unusual cases. Central adjudication and tumor coding of the five major cancers (i.e., breast, colon, rectum, endometrium, and ovary) will be carried out by the FHCRC Cancer Surveillance System (CSS) staff. Cancer cases for which the CSS staff cannot assign a final diagnosis will be forwarded to the consulting pathologist for adjudication and coding.

The UCSF Osteoporosis Study Center (subcontractor to the CCC) will be responsible for central adjudication of specific fractures.

3.3 Local Adjudication Procedures

The following outcomes will be adjudicated locally (some of these may also require central adjudication). Note that some of these outcomes are adjudicated **only** for the first occurrence in each participant. (See *Table 3.3 – Subsequent Conditions*.)

Most hospitalizations in WHI require request of at least a face sheet with ICD-9-CM codes, discharge summary, and operative report (see outcomes ascertained by self-report only that do not require investigation). Naturally, the primary WHI outcomes require the most extensive documentation. See *Table 2.1 – Documentation Requirements for WHI Outcome* for specific documents required for specific outcomes.

- **Cardiovascular disease.**

  Myocardial infarction (MI) (hospitalized only)

  Coronary death

  Stroke and transient ischemic attack (TIA) (hospitalized only)

  Congestive heart failure (CHF) (hospitalized for new or worsening only)

  Angina pectoris (hospitalized only)

  Peripheral arterial disease (hospitalized only)

  Carotid artery disease and revascularization (hospitalized only)

  Coronary revascularization procedures (including coronary artery bypass graft [CABG], coronary angioplasty [PTCA], and coronary stent or atherectomy)

- **All cancers, excluding non-melanoma skin cancers.**
- **All hip fractures.**
- **Other fractures** (in all CT participants, and in OS participants **only** at Bone Density CCs):

  Upper leg (not hip)

  Pelvis

  Knee (patella)

  Lower leg or ankle

  Foot (not toes)

  Tailbone (coccyx)

  Spine or back (vertebra)

  Lower arm or wrist

  Hand (not finger)

  Elbow

  Upper arm or shoulder (humerus)

  Collarbone; all clavicular and scapular fractures

- **Venous thromboembolic disease (HRT participants only):**

  Pulmonary embolism (PE)

  Deep vein thrombosis (DVT)

- **Hysterectomy (HRT participants only)**
- **All hospitalizations or outpatient visits that required an overnight hospitalization**, excluding the specific elective procedures listed in *Section 2.1.2.1 - Outcomes Ascertained Only By Self-Report.*
- **All deaths**

Table 3.1
Adjudication Requirements for WHI

	Type of Adjudication		Required Outcomes
OUTCOMES	LOCAL	CENTRAL	**Forms**
Deaths			
Due to CHD (Coronary death):			
In hospital	X	X	(7, 120), 121, 124, 125
Out of hospital	X	X	(7,120), 121, 124
All other:			
In hospital	X	X	(7,120), 124, 125
Out of hospital	X	X	(7, 120), 124
Cardiovascular Hospitalizations			
MI	X	X	121, 125
Negative MI (no outcome confirmed locally)		%	
Angina	X	X	121, 125
Negative angina (no outcome confirmed locally)		%	
CHF	X	X	121, 125
Negative CHF (no outcome confirmed locally)		%	
Stroke/TIA	X		121, 125
Peripheral arterial disease			121, 125
Carotid artery disease	X		121, 125
Coronary revascularization procedures (in and out patient)	X	X	121, (125)
Coronary death	X	X	121, (125)
Cancers			
Breast, endometrium, ovary, colon, and rectum			
In hospital	X	X	122, 125
Out of hospital	X	X	122
Other cancers:	X	%	122, 125
Common metastasis sites (brain, bone, liver, lung)	X	%	122, (125)
Fractures			
Hip fractures (All CT and OS):			
In hospital	X	X	123, 125
Out of hospital	X	X	123
Other Fractures (All CT and OS at BD sites):			
In hospital	X	%	123, 125
out of hospital	X	%	123
Uncertain hip (algorithm based on F123 q.1)	X	X	123, (125)
Negative hip (no outcome confirmed locally)		%	33D
All overnight hospitalization (including outpatient visits that result in a hospitalization)	X		125
HRT ONLY			
Venous thromboembolic disease	X	X	126, 125
Hysterectomy	X		131, 215

Form 7 – Participant Status
Form 120 – Initial Notification of Death
Form 121 - Report of Cardiovascular Outcome. Confirmation of a cardiovascular outcome.
Form 122 - Report of Cancer Outcome. Confirmation of incident cancer.
Form 123 - Report of Fracture Outcome. Confirmation of a fracture outcome.
Form 124 - Final Report of Death. Confirmation of a death outcome.
Form 125 - Summary of Hospitalization Diagnosis. Documentation of the hospital discharge diagnosis to determine diagnosis codes relevance to WHI-defined outcomes
Form 126 - Report of Venous Thromboembolic Disease (HRT only). Confirmation of a DVT or PE outcome for HRT participants only.
Form 131 - Report of Hysterectomy (HRT only). Confirmation of a hysterectomy for HRT participants only.

3.3.1 Physician Adjudicator Responsibilities

The Physician Adjudicator receives and reviews the adjudication case packet, determines which (if any) WHI Outcomes have occurred, completes the appropriate forms, and returns the case packet to the Outcomes Specialist within two weeks. Notify the Outcomes Specialist if after review of the case packet, the adjudicator indentifies case packets that should be merged/bundled.

3.3.1.1 Adjudication Case Packet Review

The adjudication case packet consists of:

- *Members Outcomes Status Report* (*WHIP 1215*), which provides individual participant information about confirmed outcomes, outstanding outcomes that have not been assigned to the Physician Adjudicator, and pending adjudications. Randomization/enrollment status is also listed. This information will be helpful when reviewing first versus subsequent outcomes and when determining if adjudication cases should be combined because they refer to the same event (e.g., specific cancer diagnosis or fracture treatment) and identification of Hormone Replacement Therapy [HRT] participants requiring additional outcomes forms.
- *Investigation Documentation Summary* (*IDS, WHIP 0988*), which contain specific information about the case packet documents attached and is completed by the Physician Adjudicator after the adjudication is completed.
- Medical records documents, which should be consistent with the required documentation sets identified in *Table 2.1 - Documentation Requirements for WHI Outcomes* with appropriate explanations on the IDS if not all, or additional, documents are included.
- Outcomes forms, the specific type of which should be consistent or *Table 3.1 – Adjudication Requirements for WHI.* Note that the Physician Adjudicator should have an additional supply of outcomes forms in case additional WHI outcomes are found during the adjudication. These forms include:

  Form 121 - Report of Cardiovascular Outcome. *Form 121* includes WHI cardiovascular outcomes of interest, including MI, coronary death, angina pectoris, Congestive Heart Failure (CHF), stroke, transient ischemic attack (TIA), carotid artery disease, peripheral arterial disease, and coronary revascularization. Only events requiring hospitalization or occurring **during** a hospitalization for another reason (except coronary death and coronary revascularization procedures) are counted as cardiovascular outcomes for this study. *Form 121* has been devised so that the physician completing it must interpret the diagnostic findings of the medical record, but does not need to make a distinction between “definite” or “probable” MI - a computer algorithm will make this distinction according to the WHI protocol.

  Form 122 - Report of Cancer Outcome. *Form 122* is used to report the **first** occurrence of any cancer except non-melanoma skin cancer (which is not a WHI outcome). Thus, metastases or recurrence will not be documented on this form. Second primary breast cancer **will** be recorded on this form.

  Form 123 - Report of Fracture Outcome. *Form 123* is used to report any occurrence of particular fractures. Fractures that do **not** require local or central adjudication include: ribs, chest/sternum, skull/face, fingers, toes, cervical vertebrae, or neck (these will all be self-report only). Hip and other fractures will be adjudicated for **all** CT participants. In OS participants at non-Bone Density CCs, **only** hip fractures will be adjudicated. Other fractures will be adjudicated for OS participants at Bone Density CCs only. (See *Table 3.2 – Form to be Completed for CT/OS participants*).

  Form 124 - Final Report of Death. This form should be completed when a final cause of death can be assigned. For hospitalized deaths, this will usually be when the discharge summary is available. Note that the case packet should also include documentation of the last WHI hospitalization, if applicable. An autopsy report, if done, will be sufficient to complete this form if no discharge summary is available. If there is no discharge summary or autopsy report, the form can be completed with only a death certificate.

Form 125 - Summary of Hospitalization Diagnosis. The Physician Adjudicator is responsible for the completion of *Form 125*. Alternatively, if proficient with medical terminology, the CC Outcomes Specialist (or designee) enters the ICD-9-CM codes from the Face Sheet, Physician Attestation Sheet, or other coding abstract onto the form, and the Physician Adjudicator signs that the documents have been reviewed for possible WHI outcomes.

Form 126 - Report of Thromboembolic Disease (HRT). A diagnosis of PE or DVT will prompt completion of this form for HRT participants only.

Form 131 - Report of Hysterectomy (HRT). A hysterectomy will prompt completion of this form for HRT participants only.

When reviewing the case packet, the Physician Adjudicator will decide, for each outcome, whether the relevant medical records documents are present (see *Table 2.1 – Documentation Requirements for WHI Outcomes)* For all outcomes involving a hospitalization, this documentation will include at the minimum a hospital Face Sheet, and/or Physician Attestation Sheet (including admit and discharge dates, discharge diagnoses, and, usually, ICD-9-CM codes for each discharge diagnosis and procedure). Most hospitalized outcomes also require a hospital Discharge Summary, which will include admitting signs and symptoms, initial impressions, hospital course, procedures, and final discharge diagnoses. If all required documentation is present (including those possible WHI outcomes identified in the medical records but not reported by the participant), the Physician Adjudicator may proceed in assigning a diagnosis. If the Physician Adjudicator judges the packet not to be complete, it should be returned to the CC Outcomes Specialist for further documentation. There may be instances where the complete documentation cannot be obtained. In these cases, the Physician Adjudicator should proceed with assigning a diagnosis using the available documents.

Table 3.2
Forms to be Completed for CT/OS Participants

	Initial Report of Death (120)	CVD (Hospitalized) (121)*	Cancer (incident) (122)	Hip Fracture (123)	Other Fractures (123)	Death (124)	Hospitalization (125)***	PE/DVT (126)	Hysterectomy (131)
CT	X	X	X	X	X	X	X	X (HRT only)	X (HRT only)
OS	X	X	X	X	Bone Density sites only**	X	X		

* includes outpatient coronary revascularization

** Bone Density sites: (Tucson/Phoenix, Birmingham, Pittsburgh) should investigate and adjudicate hip and other fractures in all participants. Non-bone density sites can close any fracture (other than hip) reported by an OS participant

*** Excludes the "Bunionectomy list"

Table 3.3
Subsequent Conditions

Tied to Other Incident Outcomes		
EVENT	**Adjudicate *all* events before incident MI?**	**Adjudicate *first* event after incident MI?**
Angina	Yes	No
CHF	Yes	Yes
Coronary revascularization	Yes	Yes
MI	Yes	No
EVENT	**Adjudicate *all* events before incident stroke?**	**Adjudicate *first* event after incident stroke**
TIA	Yes	No
Carotid Artery Disease	Yes	No
Stroke	Yes	No

Not Tied to Other Incident Outcomes

EVENT	**Adjudicate First event?**	**Adjudicate subsequent event?**
VENOUS THROMBOEMBOLIC DISEASE		
DVT (HRT only)	Yes	Yes
PE (HRT only)	Yes	Yes
CARDIOVASCULAR		
Peripheral Arterial Disease	Yes	No
CANCER		
Incident Cancer	Yes	No*
FRACTURE		
(BONE DENSITY SITE)		
First Hip fracture CT/OS	Yes	No
First "other fracture" (by site) CT/OS	Yes	No
(NON-BONE DENSITY SITE)		
First hip fracture CT/OS	Yes	No
First other fracture (by site) CT	Yes	No
First other fracture (by site) OS	No**	No
HYSTERECTOMY (HRT ONLY)	Yes	N/A
DEATH	Yes	N/A

* Adjudication is required if initial breast cancer is in-situ or if a second primary breast cancer is diagnosed.

** Ascertainment and adjudication of fractures other than hip, in OS participants at non-bone density sites, is not required.

First vs. Subsequent Disease

For cardiovascular diseases, in general, only the **first** occurrence (after randomization/enrollment into WHI) of a **particular** outcome will be adjudicated locally as an outcome of interest. Subsequent outcomes of the particular type are usually treated only as hospitalizations. However, subsequent hospitalized angina and CHF will be adjudicated until an MI is confirmed, and the first incident CHF event after an MI will be adjudicated. (See *Table 3.3 – Subsequent Conditions.*) Likewise, subsequent TIAs and carotid artery disease will be adjudicated until a stroke is confirmed. A second primary breast cancer will also receive full local and central adjudication. The *Members Outcomes Status Report* (*WHIP 1215)* at the front of the case packet will list all previous adjudicated and in-process WHI outcomes for that participant.

Cardiovascular Disease

Only the **first** occurrence **after WHI randomization or enrollment** of a myocardial infarction (MI), stroke, or peripheral arterial disease will be adjudicated. First and recurrent hospitalizations for angina and CHF will be adjudicated until a first MI is confirmed. A second MI occurring in a woman with a previously-assigned MI diagnosis by WHI adjudication will **not** require adjudication, but an MI occurring in a women with one or more previous WHI diagnoses of angina or CHF **will** require adjudication. Likewise, first and recurrent TIAs and carotid artery disease will be adjudicated until a first stroke is confirmed. (See *Table 3.3 – Subsequent Conditions*.)

Cancer

Only the primary occurrence of a cancer will require adjudication. A second primary breast cancer occurring in a woman who previously had a diagnosis of breast cancer will also require documentation and adjudication, however. A cancer of a different primary site developing in a woman who has previously had a cancer outcome, will always require relevant documentation and adjudication (except for non-melanoma skin cancer). A cancer metastasis will not require adjudication except to confirm that it is not a primary cancer. A percentage of common metastatic sites adjudicated locally as primary cancers will be adjudicated centrally.

Fractures

Only the **first** occurrence after WHI randomization enrollment) of a particular fracture site will be adjudicated locally. (See *Section 3.3 – Local Adjudication Procedures* for a listing of fractures requiring adjudication.)

3.3.1.2 Assigning a Diagnosis (Local Adjudication)

The adjudicator should read through the entire packet carefully, particularly the Face Sheet and Discharge Summary. Be aware that more than one outcome may be present in a packet, even though the *Investigation Documentation Summary* (*WHIP 0988)* and outcomes forms may not reflect this. Thus, all documents in a case packet, including those hospitalizations that are not thought to include WHI outcomes, should be reviewed for possible outcomes.

You may receive more than one case packet for a participant whose total documentation (e.g., diagnosis and treatment of one event) indicates only one outcome. In this case combine the case packets into one adjudication case with one outcomes form. This is referred to as "merging" cases, and is allowed in WHI for the conditions listed below.

- Inter-hospital transfer
- Intra-hospital transfer
- Cancer diagnosis, e.g., outpatient biopsy followed by tumor removal in hospital or at day-surgery
- Fracture diagnosis, e.g., X-ray at one facility followed by treatment at a different facility

Note that cardiovascular visits are adjudicated separately unless they are an inter or intra hospital transfer.

Refer to the appropriate sections in this manual for more detailed information on the diagnostic criteria for WHI outcomes.

3.3.1.3 Requesting Central Adjudication of Outcomes

The Physician Adjudicator has the option of requesting central adjudication for a case if feedback on the diagnosis is needed. The Physician Adjudicator should first make the best possible diagnosis, complete the *IDS* and any outcome forms based on the available documentation, and check a "request for central adjudication" on the *IDS* and include an explanation of that request (i.e., what issue the central reviewers should address).

3.3.1.4 Completing the Outcomes Forms and Reports

All outcomes documented within a packet must be adjudicated appropriately with relevant outcomes forms completed. The outcomes forms must include sufficient information (e.g., participant ID) to ensure they don't get mixed up with other cases. Refer to the forms instructions in Appendix A for more information on completing the outcomes forms. Only **one** *Form 121 - Report of Cardiovascular Outcome* need be completed for each CVD Outcome in a single adjudication case packet. However, a **separate** *Form 122 - Report Cancer Outcome* would need to be completed for each incident cancer outcome (excluding non-melanoma skin cancer). *Form 123 - Report of Fracture Outcome* **may** need to be completed for more than one site or more than one fracture outcome. **The number of forms to be completed is dependent on the site and side of the reported fracture** (e.g., a collar fracture that includes the radius and ulna of same side would require **one** form. Fracture of the right radius and left ulna would require completion of **two** *Form 123s).*

Any case packet that includes a hospitalization, whether or not another WHI outcome is present, requires completion of *Form 125 - Summary of Hospitalization.* (Note that some procedures, even if they require an overnight stay, may not require completion of a *Form 125*--refer to *Section 2.1.1.1 - Outcomes Ascertained Only by Self-Report*). The Physician Adjudicator is responsible for the completion of *Form 125*. If proficient with medical terminology, the Outcomes Specialist may transcribe the ICD-9-CM codes from the medical records documents onto *Form 125*. Note that ICD-9-CM codes should **not** be corrected or added (even if the Physician Adjudicator disagrees with the ICD-9-CM code as listed) but instead should be transcribed as they appear on the medical records document.

The *Investigation Documentation Summary* (*WHIP 0988*) is completed by the Physician Adjudicator after the case is adjudicated.

- Mark "Outcomes attached" if you confirm that a WHI outcome is present.
- Mark "no WHI outcome" if **no** outcome is present. You **do not** need to complete any outcome form unless there is an overnight hospitalization, which is considered a WHI outcome and requires completion of *Form 125*.
- Mark "request for more documentation" if you need additional records because you have identified an additional potential outcome or need additional records to make an accurate diagnosis. To maintain consistency across CCs request additional medical records (beyond the required documentation set) only if **essential** to make the diagnosis in a particular case.
- Mark "request for central adjudication" if you have a procedural question or are not certain of the diagnosis (you still must make a "best diagnosis," however, and include the reason for the request). Do not routinely mark this item. Clinic Centers do not need to forward these cases until they receive a request (issued monthly) for case packets to send for central adjudication. This report is based on the completed outcomes forms entered in the database.

3.3.1.5 Returning the Case Packet

Ensure that all forms, reports, and documents for each case packet are complete and stapled or clipped together before returning them to the Outcomes Specialist for data entry. The case packets should be returned in a secure envelope and via an appropriate routing system that preserves participant confidentiality.

3.4 Quality Assurance

Quality assurance of the local adjudication will be performed through comparison of centrally- and locally-assigned diagnoses. These comparisons will be made available to local adjudicators as a method of training.

In addition, the CCC, Morbidity and Mortality Committee, and Performance Monitoring Committee (PMC) have developed centralized reports of local ascertainment adjudication (e.g., timeliness). These groups will monitor local performance and make recommendations for performance enhancement and study-wide procedural changes

SECTION 3

PHYSICIAN ADJUDICATION

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